

CLAIMS:

1. A process for making a pharmaceutical composition suitable for delivery through mucosal membranes comprising:
- 5 a) preparing a pharmaceutical agent composition in micellar form in an aqueous medium which has an alkali metal salicylate in a concentration of from 1 to 10 wt./wt.% of the aqueous micellar pharmaceutical agent composition, an alkali metal C8 to C22 alkyl sulphate in  
10 a concentration of from 1 to 10 wt./wt.% of the aqueous micellar pharmaceutical agent composition and a pharmaceutically acceptable edetate in a concentration of from 1 to 10 wt./wt.% of the aqueous micellar pharmaceutical agent composition;
- 15 b) slowly adding the micellar proteinic pharmaceutical agent composition, while mixing, to at least one absorption enhancing compound, while continuing to mix vigorously, said absorption enhancing compounds being selected from the group consisting of lecithin,  
20 hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid, octylphenoxypolyethoxyethanol, glycolic acid, lactic acid, chamomile extract, cucumber extract, oleic acid, linolenic acid, borage oil, evening of primrose oil, menthol, trihydroxy oxo cholanylglycine  
25 and pharmaceutically acceptable salts thereof, glycerin, polyglycerin, lysine, polylysine, polidocanol alkyl ethers and analogues thereof, triolein and mixtures thereof, wherein the amount of each absorption enhancing  
30 10 wt./wt.% of the total formulation, and the total concentration of alkali metal salicylate, alkali metal

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2. A process according to Claim 1 wherein there is an additional step of adding, while continuing mixing, at least one absorption enhancing compound different to that added in step b), selected from the group consisting of lecithin, hyaluronic acid,

15 3. A process according to Claim 1 wherein the  
absorption enhancing compound in step b) is selected  
from the group consisting of saturated phospholipid,  
unsaturated phospholipid, phosphatidylcholine,  
phosphatidyl serine, sphingomyelin,  
20 phosphatidylethanolamine, cephalin, lecithin,  
lysolecithin and mixtures thereof.

5. A process according to Claim 1 wherein the micellar  
30 absorption enhancing compounds comprise combinations  
selected from the group consisting of i) saturated

5 6. A process according to Claim 1 wherein the  
proteinic pharmaceutical agent is selected from the  
group consisting of insulin, heparin, so-called low  
molecular weight heparin, hirulog, hirugen, huridin,  
interferons, interleukins, cytokines, mono and  
10 polyclonal antibodies, chemotherapeutic agents,  
vaccines, glycoproteins, bacterial toxoids, hormones,  
calcitonins, insulin like growth factors (IGF), glucagon  
like peptides (GLP-1), large molecule antibiotics,  
protein based thrombolytic compounds, platelet  
15 inhibitors, DNA, RNA, gene therapeutics, antisense  
oligonucleotides, opioids, narcotics, analgesics,  
NSAIDS, steroids, hypnotics, pain killers and morphine.

7. A process according to Claim 1 wherein in step b) the micellar proteinic pharmaceutical agent composition is added to lecithin, with sonication, to form a mixed micellar composition; and

c) while continuing to mix, adding at least one absorption enhancing compound selected from the group consisting of hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid, octylphenoxypolyethoxyethanol, glycolic acid, lactic acid, chamomile extract, cucumber extract, oleic acid, linolenic acid, borage oil, evening of primrose oil, trihydroxy oxo cholanylglycine, glycerin, polyglycerin, lysine, polylysine, triolein and mixtures thereof;

wherein the amount of lecithin and the absorption

14. A mixed micellar pharmaceutical formulation

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comprising a pharmaceutical agent in micellar form,  
water, an alkali metal C8 to C22 alkyl sulphate in a  
concentration of from 1 to 10 wt./wt.% of the total  
formulation, a pharmaceutically acceptable edetate in a  
5 concentration of from 1 to 10 wt./wt.% of the total  
formulation, at least one alkali metal salicylate in a  
concentration of from 1 to 10 wt./wt.% of the total  
formulation, and at least one absorption forming  
compound, said absorption forming compounds being  
10 selected from the group consisting of lecithin,  
hyaluronic acid, pharmaceutically acceptable salts of  
hyaluronic acid, octylphenoxypolyethoxyethanol, glycolic  
acid, lactic acid, chamomile extract, cucumber extract,  
oleic acid, linolenic acid, borage oil, evening of  
15 primrose oil, menthol, trihydroxy oxo cholanylglycine  
and pharmaceutically acceptable salts thereof, glycerin,  
polyglycerin, lysine, polylysine, polidocanol alkyl  
ethers and analogues thereof, triolein and mixtures  
thereof, wherein the amount of each absorption enhancing  
20 compound is present in a concentration of from 1 to  
10 wt./wt.% of the total formulation, and the total  
concentration of absorption enhancing compounds are less  
than 50 wt./wt.% of the formulation.

15. A mixed micellar pharmaceutical formulation  
25 according to Claim 14, in which one of the absorption  
enhancing compounds is lecithin.

16. A formulation according to Claim 14 wherein the  
alkali metal C8 to C22 alkyl sulphate is sodium lauryl  
sulphate and the alkali metal salicylate is sodium  
30 salicylate.

17. A formulation according to Claim 15 wherein the

18. A formulation according to Claim 15 wherein the other absorption enhancing compound is selected from the group consisting of hyaluronic acid, pharmaceutically acceptable salts of hyaluronic acid and mixtures thereof, the concentration such absorption enhancing compound being from about 1 to about 5 wt./wt. %.

19. A formulation according to Claim 14 wherein the formulation comprises combinations selected from the group consisting of i) sodium lauryl sulphate, sodium salicylate, disodium edetate, saturated phospholipid and sodium hyaluronate; ii) sodium lauryl sulphate, sodium salicylate, disodium edetate, lecithin and sodium hyaluronate; iii) sodium lauryl sulphate, sodium salicylate, disodium edetate, sodium hyaluronate and evening of primrose oil; iv) sodium lauryl sulphate, sodium salicylate, disodium edetate, saturated phospholipid and bacitracin; v) sodium lauryl sulphate, sodium salicylate, disodium edetate, saturated phospholipid, sodium hyaluronate and bacitracin; and vi) sodium lauryl sulphate, sodium salicylate, disodium edetate, sodium hyaluronate, oleic acid and gamma linoleic acid.

20. A formulation according to Claim 14 wherein the  
30 pharmaceutical agent is selected from the group  
consisting of insulin, heparin, so-called low molecular

21. A formulation according to Claim 14 wherein the pharmaceutical agent is insulin.

23. A formulation according to Claim 14 wherein the  
20 formulation additionally comprises a phenol selected  
from the group consisting of phenol, methyl phenol and  
mixtures thereof.

25. A formulation according to Claim 24 wherein the propellant is selected from the group consisting of tetrafluoroethane, tetrafluoropropane, dimethylfluoropropane, heptafluoropropane, dimethyl ether, n-butane and isobutane.

add A7  
add B2